

CLINICAL PRACTICE GUIDELINE

Bariatric Surgery

by Norbert Runkel, Mario Colombo-Benkmann, Thomas P. Hüttl, Harald Tigges, Oliver Mann, and Stephan Sauerland

SUMMARY

Background: Bariatric surgery has increased in numbers, but the treatment of morbid obesity in Germany still needs improvement. The new interdisciplinary S3-guideline provides information on the appropriate indications, procedures, techniques, and follow-up care.

Methods: Systematic review of the literature, classification of the evidence, graded recommendations, and interdisciplinary consensus-building.

Results: Bariatric surgery is a component of the multimodal treatment of obesity, which consists of multidisciplinary evaluation and diagnosis, conservative and surgical treatments, and lifelong follow-up care. The current guideline extends the BMI-based spectrum of indications that was previously proposed (BMI greater than 40 kg/m², or greater than 35 kg/m² with secondary diseases) by eliminating age limits, as well as most of the contraindications. A prerequisite for surgery is that a structured, conservative weight-loss program has failed or is considered to be futile. Type 2 diabetes is now considered an independent indication under clinical study conditions for patients whose BMI is less than 35 kg/m² (metabolic surgery). The standard laparoscopic techniques are gastric banding, gastric bypass, sleeve gastrectomy, and biliopancreatic diversion. The choice of procedure is based on knowledge of the results, long-term effects, complications, and individual circumstances. Structured lifelong follow-up should be provided and should, in particular, prevent metabolic deficiencies.

Conclusion: The guideline contains recommendations based on the scientific evidence and on a consensus of experts from multiple disciplines about the indications for bariatric surgery, the choice of procedure, techniques, and follow-up care. It should be broadly implemented to improve patient care in this field.

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Obesity is a growing medical and socioeconomic problem (e1, e2). Every second adult in Germany is overweight (Body Mass Index [BMI] ≥ 25 kg/m²), and every fifth one is obese (BMI ≥ 30 kg/m²) (e3–e5). Obesity is associated with many different illnesses, chief among them type 2 diabetes mellitus, high blood pressure (metabolic syndrome), gallstones, certain types of cancer, gastroesophageal reflux disease (GERD), fatty liver, degenerative joint diseases, obstructive sleep apnea syndrome, and psychiatric diseases. It lowers life expectancy by 5 to 20 years (e6).

The efficacy of surgery for obesity (bariatric surgery) has been demonstrated by extensive meta-analyses, with evidence level (EL) 1a (1–3). Surgery is markedly superior to conservative treatment with respect to weight reduction and alleviation of illnesses caused by obesity (EL 2b) (4, 5). It can lower the long-term lethality of obesity by as much as 40% (EL 2b) (5, 6). In a prospective, controlled study from Sweden, the absolute risk reduction (ARR) was found to be 1.3%; in an American retrospective cohort study, in which patients were observed for seven years, the ARR was 1.4%. These two figures correspond to an NNT (number needed to treat) of 76.5 and 73, respectively (EL 2b) (5, 6).

Surgery for obesity is not yet available everywhere in Germany. This interdisciplinary S3 guideline is intended to provide practical aid in decision-making for the purpose of quality assurance.

Methods

The methods used here were in accordance with the recommendations of the Association of Scientific Medical Societies in Germany (*Arbeitsgemeinschaft der Wissenschaftlich-medizinischen Fachgesellschaften*, AWMF). This guideline was developed on the basis of the existing evidence-based guideline of the European Association for Endoscopic Surgery (EAES), issued in 2005 by a group under the direction of S. Sauerland (one of the authors of this guideline) (7). Pertinent literature in English and German that appeared too late for consideration in the earlier guideline was identified by a PubMed search for papers that were published between May 2004 and April 2009 and contained the following terms: “Bariatric Surgery”[Mesh] AND (Clinical Trial[ptyp] OR Meta-Analysis[ptyp] OR Practice Guideline[ptyp] OR Randomized Controlled Trial[ptyp]) AND (“2004/05” [PDAT]; “2009/04” [PDAT]). This search yielded 337 hits.

Evidence levels (EL) were graded according to the scheme of the Oxford Centre for Evidence-Based Medicine. Thus, the literature was restricted as much as

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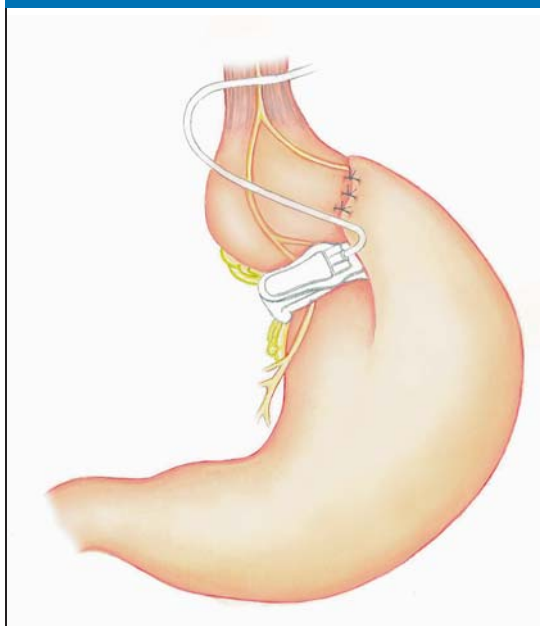
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FIGURE 1



Gastric banding: An adjustable gastric band is used to divide the stomach into a small proximal compartment (pouch) and a larger distal compartment (residual stomach).

possible to randomized and non-randomized comparative trials. Recommendations are given in three different strengths (grades); the strength of each recommendation is reflected in its wording (“must” vs. “should” vs. “may”). Two formal consensus conferences took place for the development of an interdisciplinary consensus on the guideline’s recommendations. All recommendations were made on the basis of a “strong consensus,” i.e., with the agreement of more than 95% of the participants. The manuscript was submitted to the presidents of the participating specialty societies for comment. The final version was approved by the panel of experts (<http://www.awmf.de>).

Results

Diagnostic Assessment and Preoperative Evaluation

Before the patient is selected for surgery, a physician with experience in the conservative treatment of obesity (e.g., a physician nutrition specialist) must be consulted for an opinion. It is also essential for the patient to undergo treatment preoperatively by an expert in nutrition, i.e., a dietician or ecotrophologist with training equivalent to that of a dietician according to the German Law on Dieticians [*Diätassistentengesetz*]. Treatable causes of obesity, such as hypothyroidism, must be ruled out. Gastrosocopy is obligatory. Further specialists should be consulted depending on whatever associated illnesses the patient may have. Among obese persons, exertional dyspnea becomes more common with increasing BMI: its prevalence is 57.5% when the BMI is less than 50 kg/m² and 100% when it exceeds 50 kg/m² (EL 2b) (e7). Polysomnography reveals sleep apnea syndrome in 40% to 91% of patients aged 30 to 50 with BMI above 40 kg/m² (EL 4) (e8, e9).

For every patient, one should consider consulting a clinical psychologist, a physician specializing in psychosomatic medicine, or a psychiatrist, as the prevalence of affective disorders, anxiety disorders, eating disorders, and personality disorders increases with increasing BMI (EL 2b) (e10, e11). Recommendations have been issued regarding the contents of the psychological assessment (8). Mental illnesses can be used neither as an indication criterion, with the exception of a very small number of conditions, such as bulimia nervosa (EL 2a) (9), nor as a predictor of postoperative weight loss (EL 4) (10). It follows that the proper role of psychological assessment lies, not in gatekeeping, but rather in screening and preparing for the operation (EL 4) (8, 11).

Indications

The new guideline adopts, in nearly unchanged form, the recommendation issued by the National Institutes of Health (NIH) in 1991 (e12) that bariatric surgery should be performed when conservative treatment has failed in patients whose BMI exceeds 40 kg/m², or 35 kg/m² in the presence of comorbidities. The words “when conservative treatment has failed” are newly replaced by the words “when conservative treatment has been exhausted”: this is said to have occurred when the treatment goal of 10% to 20% weight loss in a patient whose BMI is 35 to 40 kg/m², or 10% to 30% in a patient whose BMI exceeds 40 kg/m², cannot be reached and maintained in 6 to 12 months of treatment. Conservative treatment should consist of appropriate modifications of diet, exercise, and behavior, as long as there are no barriers to such measures, such as osteoarthritis of the knee limiting walking, embarrassment limiting swimming, physical inability to travel to the centers where such measures are performed, or shift-work. Psychotherapy is not required in every case. The following criteria are useful in preoperative assessment:

- Nutrition: Maintenance of a mixed low-calorie diet and one further nutritional measure, e.g., a formula diet.
- Exercise: At least two hours’ participation in an endurance or strength/endurance sport per week.
- Psychotherapy: In- or outpatient psychotherapy (behavior therapy or depth psychology) when the patient is suffering from an eating disorder (binge-eating, night-eating) or a mental disturbance (e.g., depression, anxiety).
- Patient group: Life-style modification therapy in a group, if possible.

Surgery may be indicated as primary treatment, i.e., without prior conservative treatment, if the latter is considered to have no chance of success. The indication is urgent if the patient’s morbidity or other psychosocial factors imply that his or her health would worsen rapidly without surgery. The decision whether an operation is indicated should be made by a physician qualified in the treatment of obesity together with a bariatric surgeon.

In the new guideline, type II diabetes mellitus is held to be an independent indication criterion for patients whose BMI lies between 30 and 35 kg/m²; in the pertinent literature, surgery for this indication is known as

metabolic surgery (e13). Patient selection for metabolic surgery should be strict, and all patients should be entered into clinical studies, e.g., the quality-assurance study of the German Society for General and Visceral Surgery. The remission rate of type II diabetes after this type of surgery is, on average, 76.8% (EL 1a) (3). In a randomized, controlled trial (RCT) on diabetic persons with BMI between 30 and 40 kg/m², the loss of excess weight at two years was 62.5% in patients who had undergone gastric banding, compared to only 4.3% in those who had been treated conservatively; diabetes went into complete remission in 73%, compared to 13% of the conservatively treated group (definition of remission: fasting blood sugar < 126 mg/dL; HbA_{1c} < 6.2% without any need for medication) (EL 1b) (12). The remission of diabetes after gastric band implantation is correlated with weight loss.

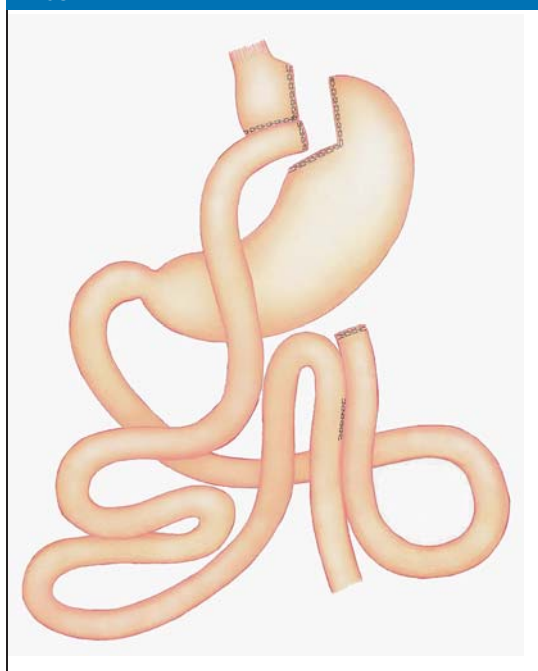
The antidiabetic effect arises earlier after gastric bypass surgery or biliopancreatic diversion than it does after gastric banding (EL 4) (13). In the first three months after surgery, 37.5% of gastric bypass patients, but only 21.0% of patients who had undergone gastric banding, can set their medications aside entirely; at 12 months, the corresponding figures are 75.0% and 36.4% (EL 4) (e14). According to the meta-analysis of Buchwald et al., the remission of diabetes remained stable for at least two years (EL 2b) (1–3), although the remission rate at ten years in a Swedish longitudinal study was 36%, considerably lower than it had been at two years (72%) (EL 2b) (5). There have been long-term observations of diabetes recurrence rates as high as 43% (EL 4) (e15, e16). It can be calculated from the findings of an RCT that the ARR for metabolic syndrome treated with gastric banding is 21.6% at two years, which corresponds to an NNT of 4.6 (EL 1b) (14).

The new guideline dispenses with the traditional upper and lower age cutoffs. For adolescents, surgery remains the last resort, and the decision to operate should be taken with utmost care by a team of experts. Contraindications include intractable diseases or wasting diseases of any kind, unstable mental illness, substance dependency, and lack of patient compliance with the recommended dietary changes and follow-up care.

Operative techniques and complications

In Germany, the following types of bariatric surgery have become established as standard techniques: gastric banding (*Figure 1*), gastric bypass (*Figure 2*), sleeve gastrectomy (*Figure 3*), and biliopancreatic diversion (BPD) with duodenal switch (*Figure 4*). These techniques are all based on two mechanisms: restriction, in which the reduced size of the gastric reservoir leads to a diminished input of food, and malabsorption (also called malassimilation), in which the digestive juices mix with food at a later time than normal. Both mechanisms contribute to early satiety. The primary intervention should be performed laparoscopically to minimize the risk of wound infection and incisional herniation. The frequency of postoperative wound infection is then less than 3%, while the rate of severe postoperative complications is less than 1% for gastric banding and less than 5% for the other techniques. These complications include postoperative hemorrhage (less

FIGURE 2



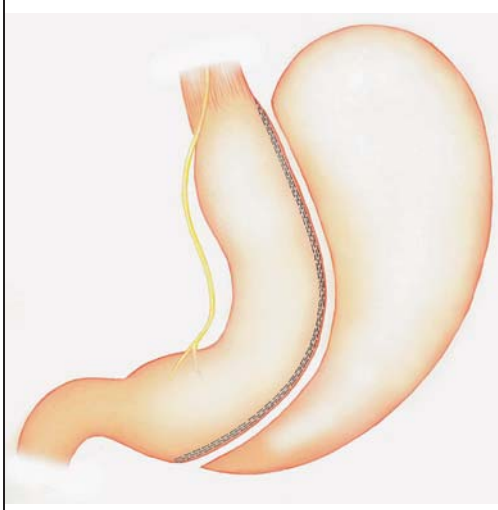
Roux-en-Y gastric bypass: The stomach is taken down a few centimeters distal to the gastric inlet. The jejunum is divided 50 cm beyond the ligament of Treitz, and its aboral end is connected to the small gastric pouch. Some 150 cm distal to this point, the other end of the small bowel is sewn to a loop that has been pulled up to meet it (so-called Roux-en-Y reconstruction). Mechanism of effect: restriction, with an additional malabsorptive component.

than 3%) and staple-line dehiscence. Thromboembolism may occur despite risk-adapted therapeutic anticoagulation: in the German quality-assurance study, pulmonary embolism arose and was treated in 0.06% of 3122 patients who had undergone bariatric surgery, usually after their discharge from the hospital (EL 4) (e17). According to review articles on the subject, the operative mortality is 0.1% for gastric banding, 0.2% for gastric bypass, 0.7% for BPD (EL 1a) (2), and 0.3% for sleeve gastrectomy (EL 4) (15).

The surgeon's experience affects postoperative morbidity (EL 4) (16, e18) and mortality; the latter can be 6.2 times higher in the hands of a surgeon who does fewer than 20 such procedures per year (EL 4) (e19). Thus, bariatric surgery should be performed by surgeons with the requisite special experience, in hospitals where these operations are commonly performed. Certification in bariatric surgery by the specialty society in Germany requires a minimum of 50 cases per year for a competence center and 100 per year for a reference center (e20).

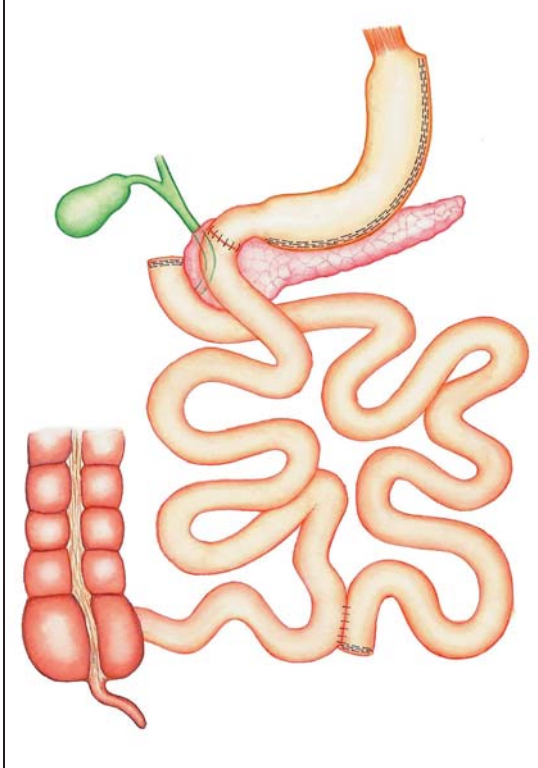
The two-year mortality ranges from 0 after sleeve gastrectomy to 1.7% after BPD (EL 1a) (2). Late surgical complications are mainly to be seen after gastric banding (EL 2b) (17): slippage and migration occur in 5.5% of cases and necessitate the laparoscopic removal of the band, while local port complications can be dealt with in a simple revision procedure. In view of the the highly

FIGURE 3



Sleeve gastrectomy: More than 80% of the stomach is resected, and the gastric remnant is tubularized, with an initial filling volume of less than 100 ml. Mechanism of effect: restriction and hormonal mechanisms.

FIGURE 4



Biliopancreatic diversion (BPD) with duodenal switch (DS): First, the stomach is reduced in size as in sleeve gastrectomy. Next, the duodenum is divided distal to the pylorus, and the jejunum is divided 250 cm proximal to the ileocecal valve and anastomosed to the duodenum. The other end is connected to the ileum 100 cm proximal to the ileocecal valve. Mechanism of effect: a combination of restriction with a considerable degree of malabsorption.

elective nature of bariatric surgery, patients must be thoroughly informed of all possible complications before consenting to the procedure.

Surgery in a stepwise fashion can lower the perioperative risk and should be considered for patients who are extremely obese (BMI > 50) and/or have major comorbidities. Thus, sleeve gastrectomy might be used as the first step, to be followed by a gastric bypass or BPD. In some cases, one may consider placing a gastric balloon endoscopically for short-term weight loss as a preparatory adjunct to surgery.

Further recommendations include: performing cholecystectomy at the same surgical session for symptomatic patients; and deferring hernia operations until weight loss is complete, because of the lesser operative trauma and the potentially lower rate of infection. The new guideline is the first to recognize post-bariatric plastic surgical corrective procedures as an integral component of the overall treatment concept.

The choice of technique

Differences in efficacy were studied in the very extensive meta-analyses by Buchwald et al. (EL 1a) (1–3). The loss of excess weight ranges from 47.5% with gastric banding to 61.6% with gastric bypass and 70.1% with BPD, with or without duodenal switch (EL 1a) (1). In a randomized controlled trial, it was found that extremely obese patients (BMI > 50 kg/m²) attained a lower body weight at 12 months with BPD than with gastric bypass (32 vs. 38 kg/m²; $p < 0.001$) (EL 1b) (18). The rate of remission of diabetes mellitus is 57% after gastric band implantation, 80% after gastric bypass, and 95% after biliopancreatic diversion (EL 1a) (3). Similar differences, in the same order, are seen with respect to the improvement of other disease states caused by obesity.

These meta-analyses did not include any data on sleeve gastrectomy, a newer technique. Other studies show that the loss of excess weight after sleeve gastrectomy is significantly higher than after gastric banding (58% versus 42% at 1 year and 66% versus 48% at 3 years) (EL 1b) (19) and about the same as after gastric bypass (70% versus 61% at 1 year) (EL 1b) (20). A recent meta-analysis documented a 66% remission rate of diabetes mellitus after sleeve gastrectomy (EL 2b) (21). Data on outcomes five years after surgery are not yet available, nor is there any information about reoperation rates (EL 4) (22, 23).

There is no gold standard in bariatric surgery, nor is there, at present, any standardized method of selecting an appropriate surgical technique on the basis of objective findings. The choice of procedure is clearly influenced by the patient's BMI, age, sex, adherence, and psychosocial status. Although the different surgical techniques are in competition with one another for selection as primary treatment, they can also complement one another when they are used in planned stepwise surgery and in revision procedures.

Postoperative care

After maximal loss of weight in the second year after bariatric surgery, the patient's weight can rise again up to

the fifth year. Thereafter, in the Swedish longitudinal study, weight was found to remain stable at 19.9 kg below the initial value (EL 2b) (4, 5). The percentage of patients who achieved sustained loss of more than 20% of their initial weight was 73.5% after gastric bypass and 27.6% after gastric banding. Weight loss was associated with significant improvements of the quality of life, physical activity, hypertension, diabetes, and abnormalities of lipid metabolism, as well as with a lower incidence of, and a lower mortality from, cardiovascular and other diseases related to obesity.

In the aftermath of surgery, the patient must receive long-term follow-up care from a physician specialized in the treatment of obesity and from an expert in clinical nutrition. The purpose of follow-up is not just to achieve a greater loss of weight (EL 4) (24, e21), but also to prevent nutritional deficiencies. The frequency of follow-up appointments depends on the particular type of procedure that was performed, the dynamics of weight loss in the individual patient, and any problems and complications that may arise. Patients should be seen every three months in the first year after surgery, because this is the period of most rapid weight loss. A well-balanced diet is best from a nutritional-medical point of view; it should be accompanied during the phase of rapid weight loss (or permanently, after gastric bypass or BPD) by the supplementation of vitamins (B12 and D), trace elements (iron), minerals (calcium), and, if necessary, protein. There is no generally accepted scheme for laboratory monitoring and dietary supplementation (e22). The dosage of some medications may need readjustment.

About one patient in ten needs to undergo further surgery at a later time because of inadequate weight loss, regained weight, or early or late complications, including gastric pouch dilatation, impaired pouch emptying, reflux, esophageal dilatation, ulceration, dumping syndrome, slipping or erosion of the gastric band, anastomotic stenosis, and ileus (e23). Laparoscopic revision operations are technically complex and carry higher complication rates; thus they should only be performed in centers with the requisite expertise.

Women of childbearing age who undergo bariatric surgery should use contraception during the rapid phase of weight loss to prevent malnutritional developmental disturbances in the unborn child.

Postoperative treatment by a psychologist, a physician specializing in psychosomatic medicine, or a psychiatrist is recommended for patients who were mentally ill before surgery, and for those who develop eating attacks afterward (binge eating disorder, night eating). If mental illness should arise or recur after surgery, specialized treatment is indicated. Participation in self-help groups is recommended, as it can reinforce weight loss (EL 4) (e24).

Discussion

Overweight and obesity have assumed epidemic proportions. Over the last ten years, the number of bariatric surgical procedures performed worldwide has risen by 761%. In 2008, 344 221 such procedures were performed, 220 000 of them in North America alone (35). In

BOX

List of the participating medical specialty societies and organizations, and of the experts nominated by them for the preparation of the guideline

The Surgical Working Group for the Treatment of Obesity of the German Society for General and Visceral Surgery:

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German Obesity Society:

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German Society for Nutritional Medicine:

Prof. Dr. A. Weimann, Leipzig

German Society for Psychosomatic Medicine and Psychotherapy:

Prof. Dr. M. de Zwaan, Erlangen

Methodological advisor (Literature search and assessment):

Prof. Dr. S. Sauerland, Cologne

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Germany, 2117 bariatric procedures were performed; Germany thus ranked behind France (13 722), Belgium (8700), the United Kingdom (6000), Spain (6000), Italy (4842), the Netherlands (3500) and Greece (2875), and barely ahead of Denmark (2004) and Austria (1741). Thus, the rate of bariatric surgery in Germany is relatively low, even though more than one million adult Germans are morbidly obese (BMI ≥ 40).

The evidence-based recommendations of the new S3 guideline are intended as an aid in the development of bariatric surgery in Germany with the necessary accompanying quality control. The guideline highlights a strong consensus among surgeons, internists, and psychotherapists to the effect that surgery is now an established component of a multimodal treatment concept. Both the preparation of the patient for surgery and the follow-up care after it should be interdisciplinary. Surgery is indicated only if conservative treatment has no prospect of helping the patient or has already been exhausted. The traditional spectrum of indications (BMI over 40 kg/m², or

over 35 kg/m² with comorbidities) has now been extended somewhat through the abolition of age cutoffs, the deletion of some conditions previously held to be contraindications, and the selective introduction of metabolic surgery for type II diabetes. Laparoscopy is the approach of choice for primary surgery. Gastric banding, gastric bypass, and biliopancreatic diversion with duodenal switch are standard procedures; sleeve gastrectomy now counts as one as well, particularly as a component of stepwise treatment for extreme obesity. The selection of the appropriate procedure is based on the patient's initial weight and a number of other individual criteria. Bariatric surgery should be performed by surgeons who are well-versed in it, and in hospitals that have the requisite institutional experience.

Conflict of interest statement

PD Dr. Hüttl has received reimbursement of travel expenses, lecture honoraria, and fees for leading doctors' training courses, which were paid to the external funding account of his own department and that of the Klinikum Grosshadern, from the Aesculap Academy, Tuttlingen and Berlin, GORE Germany; the European Surgical Institute, Covidien Germany; and Ethicon Endosurgery, Nycomed Germany.

PD Dr. Sauerland has received lecture honoraria and support for envisioned research from Ethicon Endosurgery Europe.

Prof. Dr. Runkel has received lecture honoraria from Ethicon Endosurgery Germany, Covidien Germany, Smith & Nephew Europe, B. Braun Germany, and Storz Germany.

Dr. Tigges, PD Dr. Mann und PD Dr. Colombo-Benkmann declare that no conflict of interest exists.

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